## REMARKS

Claims 1-6 and 10-16 are currently pending. The descriptive support for the amendments to claims 1-3 can be found in page 12, lines 12-13, of the specification. Applicants submit that the amendment to claim 2 is editorial and would not narrow the scope of the claim. The descriptive support for the amendments to claim 14 can be found in page 22, line 7 to page 24, line 14, of the specification.

**Claim Rejections – 35 U.S.C. § 112, second paragraph**

Applicants respectfully traverse the rejections of claims 1-3 as allegedly being unclear. A person skilled in the art would readily understand that claim 1 is drawn to fexofenadine hydrochloride characterized by the power X-ray diffraction (PXRD) peaks recited in claim 1. Because only crystalline forms are characterized by PXRD peaks, the person would know that the fexofenadine hydrochloride of claim 1 refers to any crystalline forms, including solvated or non-solvated crystalline forms, of fexofenadine hydrochloride characterized by the recited PXRD peaks. The person would also understand that claim 2 is drawn to the crystalline fexofenadine hydrochloride of claim 1 having the PXRD pattern substantially as depicted in Fig. 6. The Examiner alleged that applicants were self conflicting by pointing out that, page 12, lines 11-16, of the specification discloses that fexofenadine hydrochloride Form IX is a solvate of cyclohexane or MTBE. Applicants respectfully disagree that the disclosure regarding Form IX being the cyclohexane or MTBE solvate in page 12 conflicts with the subject matters of the claims. Crystalline fexofenadine hydrochloride can include any crystalline forms such as solvates of fexofenadine hydrochloride. Claim 3 is clear to the person skilled in the art as directed to fexofenadine hydrochloride Form IX. According to page 12 of the specification, Form IX is a solvate of cyclohexane or methyl t-butyl ether. In addition, page 12 of the specification discloses that Form IX is also characterized by the PXRD pattern recited in claims 1 and 2. The person skilled in the art would understand claims 1 and 2 to be directed to not just Form IX because claims 1 and 2 cover any crystalline fexofenadine hydrochloride, including Form IX, having the PXRD characteristics recited in these claims. The disclosure in page 12 of the specification that

fexofenadine hydrochloride Form IX is the cyclohexane solvate or MTBE solvate does not conflict with claims 1 and 2 directed to any fexofenadine hydrochloride crystalline forms having the PXRD characteristics recited in the claims. The Office Action appears to maintain the indefiniteness rejections because the claims do not recite a solvate. Applicants submit that the chemical nature of the products according to claims 1-3 is clear to the person skilled in the art, without any recitation of a solvate, since solvates can be some of the crystalline forms. Withdrawal of the indefiniteness rejections is requested.

**Claim Rejection – 35 U.S.C. § 112, first paragraph**

Applicants respectfully traverse the rejection of claim 15 under 35 U.S.C. § 112, first paragraph allegedly for nonenablement. The Office Action asserts that the processes such as wet dispersion disclosed in pages 22-24 of the specification used to make the formulation will clearly transform any crystalline form. Applicants disagree. The unit dosage of claim 15 is a pharmaceutical composition comprising a solid fexofenadine hydrochloride Form IX solvate of MTBE or cyclohexane. There is no evidence that the crystalline fexofenadine hydrochloride Form IX-MTBE solvate or Form IX-cyclohexane solvate is metastable. Applicants submit that, based on the disclosures of the specification, the unit dosage of claim 15 can be prepared by one skilled in the art without undue experimentation. Withdrawal of the non-enablement rejections is requested.

**Claim Rejections – 35 U.S.C. § 102(b)**

I. Applicants respectfully traverse the rejections of claims 1 and 2 as allegedly anticipated by Ortyl '872 (US 5,738,872).

The crystalline fexofenadine HCl disclosed in Table 19 of Ortyl '872 is different from the fexofenadine HCl crystalline forms of claims 1 and 2 because, with conversion of the d spacing values to degrees two theta, the crystalline fexofenadine HCl disclosed in Table 19 of Ortyl '872 lacks at least the following PXRD peaks: 4.7, 9.3, 19.4, 19.6 and 21.6 degrees 2θ recited in claim 1 and substantially as depicted in Fig. 6 recited in claim 2. The Examiner would not accept applicants' argument that the fexofenadine HCl of

claims 1 and 2 is different from the crystalline fexofenadine HCl disclosed in Table 19 of Ortyl '872 because the Examiner has found at least one identical PXRD peak. Applicants contend that Ortyl '872 fails to anticipate claims 1 and 2 because Ortyl '872 does not disclose crystalline fexofenadine HCl having all the characteristic PXRD peaks recited in claim 1 and 2. The Examiner stated that "mere allegation by attorney does not provide side by side comparison showing no artifacts in inter-laboratory data collection." However, the Examiner did not provide any evidence that the PXRD peaks recited in claims 1 and 2 were based on data collected improperly. The fact that the fexofenadine HCl Form II disclosed in Table 19 of Ortyl '872 lacks at least the PXRD peaks at 4.7, 9.3, 19.4, 19.6 and 21.6 degrees 2θ for the fexofenadine hydrochloride methyl t-butyl ether solvent according to claims 1 and 2 is not a "mere allegation by attorney." Based on these differences between Ortyl '872 and claims 1 and 2, withdrawal of the anticipatory rejections of claims 1 and 2 over Ortyl '872 is requested.

II. Applicants respectfully traverse the rejection of claim 16 as allegedly anticipated by Carr (US 4,254,129).

Applicants note that Examples 2 and 3 of Carr merely disclose fexofenadine hydrochloride recrystallized from butanone and methanol-butanone (Example 2) or from methanol-butanone (Example 3). Carr does not disclose the fexofenadine hydrochloride solvate of methyl t-butyl ether or cyclohexane. As a result, Carr does not disclose the pharmaceutical composition of claim 14 administered in the method of claim 16 to inhibit the binding between an H1 receptor and histamine in a mammal. Withdrawal of the anticipatory rejection of claim 16 over Carr is requested.

**Claim Rejections – 35 U.S.C. § 103(a)**

Applicants respectfully traverse the rejections of claims 1-3 and 14-16 as obvious under 35 U.S.C. § 103(a) over Ortyl '872 (US 5,738,872) in view of Evans, US Pharmacopoeia and Brittain.

Ortyl '872 differs from claims 1-3 and 14-16 at least in not disclosing the fexofenadine hydrochloride crystalline forms with the characteristic PXRD peaks recited in claim 1 or substantially as depicted in Fig. 6. The four crystalline forms of

fexofenadine hydrochloride disclosed by Ortyl '872 are different from the fexofenadine hydrochloride solvate according to claims 1-3 and the Form IX-MTBE solvate or Form IX-cyclohexane solvate in the pharmaceutical composition of claim 14, the unit dosage of claim 15 and the pharmaceutical composition administered in the method of claim 16. Evans, US Pharmacopoeia and Brittain fail to cure the deficiencies of Ortyl '872 because Evans, US Pharmacopoeia and Brittain are silent on the fexofenadine hydrochloride crystalline forms. The Office Action takes a position that the fexofenadine hydrochloride solid according to claims 1-3 and 14-16 is merely the fexofenadine HCl crystalline forms of Ortyl '872 with inclusion of impurities. Applicants disagree. There is no evidence that the inclusion of impurities in the fexofenadine HCl crystalline forms of Ortyl '872 would result in the PXRD peaks recited in claim 1 or the PXRD pattern depicted in Fig. 6 as recited in claim 2. Evans, US Pharmacopoeia and Brittain do not provide any teaching or suggestion to modify the disclosures of Ortyl '872 to arrive at the claimed invention. Thus, claims 1-3 and 14-16 would not have been obvious over the prior art relied upon by the Office Action.

Withdrawal of the obviousness rejections of claims 1-3 and 14-16 is requested.

The Examiner is urged to call the undersigned if there remains any minor issues that can be resolved with a telephone interview.

In the event that the filing of this paper is deemed not timely, applicants petition for an appropriate extension of time. The petition fee and any other fee that may be required in relation to this paper can be charged to Deposit Account No. 11-0600.

Respectfully Submitted,
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